DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

April 17, 2001

VIA FEDERAL EXPRESS

Thomas Andersen
Responsible Head
Baxter Healthcare
State Route 120 and Wilson Road
Round Lake, IL 60073

WARNING LETTER
(01-ATL-42)

Dear Mr. Andersen:

During an inspection of Sera-Tec Biologicals Limited Partnership located at 1308 West Broad Avenue, Albany, GA 31707, conducted on March 28 through April 5, 2001, our investigator documented violations of Sections 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act, and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Donor screening personnel (on at least 3 occasions since 12/12/00) failed to identify prospective new donors as persons who were previously permanently deferred. Donor screening personnel are failing to adequately review deferral and active donor lists. For example one donor had another file under a separate permanent donor number, however the donor was processed as a new applicant donor. Even though your firm's QA audit caught this error on 3/14/01; no formal investigation was initiated until this inspection. Our inspection documented two additional occasions where permanently deferred donors were allowed to donate as new donors. These deferred donors were allowed to donate. Corrective measures already implemented by your firm have not been effective as evidenced by the donor screening deviations noted during our inspection.

2. Your firm shipped a total of seven (7) plasma units after receiving confirmatory positive syphilis test results. You failed to properly act on the positive test results. Personnel failed to properly review test results, verify the bleed number and match it to the correct donor. The positive syphilis test results were filed in another donor' s chart. Personnel responsible for shipping failed to identify missing test results and thus allowed the shipment of the subject units.

3. You failed to investigate an adverse reaction and maintain appropriate records. One donor record indicated that there was a donor reaction; however there was no documentation describing the events surrounding the donor reaction, an evaluation of the donor, and an investigation of the donor reaction. Your own SOPs require a full explanation of the donor reaction including signs and symptoms; corrective measures taken to stabilize the donor; and a final outcome of the efforts and actions employed to effectively manage the reaction or medical condition.

4. On at least three (3) occasions within the last 12 months, your firm shipped units which under your SOPs, would not have been shipped. (Two occasions where the plasma was collected from a one-time donor who failed to return within 30 days for a second donation; and a third occasion where one unit was shipped from a donor with a reported abnormal ALT test results).

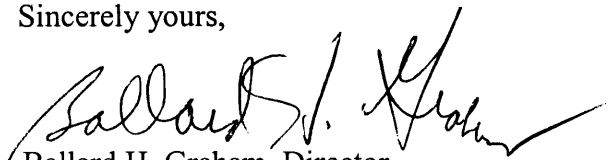
Neither this letter, nor the Form FDA 483, Inspectional Observations, issued at the conclusion of the inspection to Ms. Terri G. Macolly, Manager, is intended to be an all-inclusive list of deficiencies at your facility. A copy of the Form FDA 483, Inspectional Observations, is attached. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Serene A. Kimel, Compliance Officer at the address in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure

Cc: Mr. Roger Brinser, Director of Regulatory Affairs
Sera-Tec Biologicals Limited Partnership
931 North 7th Street
Harrisburg, PA 17102

Ms. Terri G. Macolly, Manager
Sera-Tec Biologicals Limited Partnership
1308 West Broad Avenue
Albany, GA 31707